GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:373
ANSWERED ON:03.02.2017
Affordable Medicines
Vanaroja Smt. R.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the BRICS nations are considering signing a Memorandum of Understanding (MoU) to work on mutual recognition, sharing information and accelerating regulatory approvals in case
of international and national health emergencies;

(b) if so, the details thereof;

(c) whether the BRICS regulators have agreed on a draft MoU on regulatory collaboration with a view to improve the standards, certification and regulatory mechanisms for drugs and pharmaceuticals and promoting the availability of safe, efficacious, affordable and quality medicines; and

(d) if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): The 6th BRICS Health Ministers meeting held at New Delhi recognized the need for concluding a Memorandum of Understanding (MoU) on regulatory collaboration between the drug regulatory authorities of BRICS countries with a view to improving the regulatory standards, certification and systems for medical products.

(c) & (d): The following areas have been identified for collaboration between BRICS drug regulatory authorities:
(i) Regulation of medical products, Medical Devices, Biological Products, Active Pharmaceutical Ingredients (APIs).

(ii) Pharmacovigilance,

(iii) Pharmacopoeia and quality of medical products.

(iv) Sharing of regulatory experience.